

The presence of the device 26 and user key card 200 packaged together in the kit 200 verifies to the physician or user that device 26 is sterile and has not be subjected to prior use. The physician or user is thereby assured that the device 26 meets established performance and sterility specifications. No unused device 26 is supplied in the kit 200 without a usage key card 202, and vice versa.

The usage key card 202 incorporates a storage medium 204 that is readable by the module 48. The storage medium 204 contains information that enables at least two use control and monitoring functions.

The first use control and monitoring function of the usage key card 202 occurs prior to use of the device 26 in association with the generator 38. To enable use of the generator 38 in association with the device 26, the physician must first present the usage key card 202 for reading by the module 48. To enable use of the device 26, the controller 54 must then find that the usage key card 202 meets the criteria necessary for its registration by the controller 54. The criteria are designed to indicate the absence of a prior use, either in absolute terms or in terms of a period of use outside a predetermined time period. If the criteria are not met, the controller 54 will not register the usage key card 202, and the controller 54 will also not enable use of the generator 38 in association with the device 26. Further details of the registration function of the controller 54 will

be described later.

5 The second use control and monitoring
function of the usage key card 202 occurs if the
criteria are met and registration of the usage key
card 202 occurs. During permitted use of the device
26 in association with the generator 38, the storage
medium 204 of the usage key card 202 remains in the
module 48 and receives, via the module 48, data
generated by the controller 54 recording operating
10 parameters and performance of the device 26. The
storage medium 204 of the usage key card 202 retains
and organizes the data for further off-line storage
and processing. Further details of the data
retention function will be described later.

15 The usage key card 202 can be variously
configured. In the illustrated embodiment (see Fig.
7), the usage key card 202 comprises a computer-
readable storage medium 204 housed within a
conventional 3.5 inch floppy disk 206. In this
20 arrangement, the module 48 comprises a conventional
floppy disk drive 208 (see Fig. 8) capable of
reading data from and downloading data to the
storage medium 204 of the disk 206.

25 Alternatively, the usage key card 202 can
take the form of a PC card, flash memory device, or
magnetic card. In these alternative embodiments, the
module 48 comprises a data reading and writing
device compatible with the storage medium of the
card 202.

30 As Fig. 7 shows, the storage medium 204 of
the usage key card 202 contains at least two pre-
formatted files 210 and 212. The first file 210

contains a unique identification code 214 capable of being read by the module 48 and registered by the controller 54. The second file 212 is formatted to receive and retain operational and performance data generated by the controller 54 to create from it a procedure log 220.

The identification code 214 contained in the first file 210 is created to be unique to the particular usage key card 202. That is, each usage key card 202 contains its own unique identification code 214. No two usage key cards share the same identification code 214. The unique identification code 214 can comprise, e.g., a serial number uniquely assigned to the particular device 26 found in the kit 200, or any other unique code that is not repeated for any other usage key card 202. The code 214 itself can comprise letters, numbers, or combinations thereof.

As Fig. 8 shows, the module 48 reads the identification code 214 off the usage key card 202 for input to the controller 54. This identification code will be called the "instant identification code."

Following pre-programmed rules, the controller 54 constructs and maintains in non-volatile memory a use table 216. The use table 216 contains all prior identification codes that meet the criteria to be registered by the controller 54. These identification codes will be called the "registered identification codes."

Following pre-programmed rules, the controller 54 compares the instant identification